

Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

PBM-2016-07

AUGUST 12, 2016

ITEM: PharmaTech LLC Issues Voluntary Nationwide Recall Due to Potential Risk of Product Contamination

SPECIFIC INCIDENT(S): PharmaTech LLC announced a voluntary recall expansion to include all liquid products from October 20, 2015 through July 15, 2016 due to a potential risk of product contamination with *Burkholderia cepacia* (*B. cepacia*).

GENERAL INFORMATION:

- Contamination with *B. cepacia* may result in infections in patients with compromised immune systems and in patients with chronic lung conditions such as cystic fibrosis. Some of these infections may be serious or even life-threatening in the at risk patient population.
- Affected products include **all oral liquid drug and dietary supplement products listed on pages 3-6**. Affected products were manufactured in PharmaTech LLC's Davie, Florida, facility; they are distributed and labeled by six firms – Rugby, Major, Bayshore, Metron, Centurion, and Virtus.
- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 11043** (available at: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>).
- Healthcare providers and laboratories should be on alert for *B.cepacia* cases occurring among non-cystic fibrosis patients and should inform infection prevention staff when these infections occur. Cases should be reported to state or local public health authorities.
- Providers should continue to report any adverse reactions with the use of affected oral liquid drug and dietary supplement product(s) by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>, or by mail).

ACTIONS:

PROVIDER NOTIFICATION:

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, infectious disease specialists, pulmonologists, and pharmacy staff, including contract**

providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.

- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 8/26/2016):
 - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data will be provided by CMOP representative to Pharmacy Chiefs.
 - If an affected lot(s) was dispensed to a patient(s) for home administration, then:
 - Identify the patient(s).
 - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
 - A sample letter can be found at:
<https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template.doc>.
 - This template can be altered according to site-specific needs.
 - Provide patient(s) in possession of the recalled product with instructions on the following:
 - How to return the product being recalled to the pharmacy.
 - How to obtain a new supply of product.
 - Patients should not continue to take the product until they obtain replacement product.
 - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
 - In the event patients feel ill (such as fevers and chills), they should seek immediate medical care and inform their provider that they had taken affected oral liquid products.
 - Communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the VHA Alerts and Recalls Website:
<http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>.

SOURCE: FDA

REFERENCE(S): PharmaTech LLC Issues Voluntary Nationwide Recall Due to Potential Risk of Product Contamination. <http://www.fda.gov/Safety/Recalls/ucm515610.htm> . Accessed August 11, 2016.

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.

Drug Products

Rugby:

- Diocto Syrup, Docusate Sodium 60mg/15 mL, NDC 0536-1001-85, Lot#22941505, Exp. Date 10/2017
- Diocto Syrup, Docusate Sodium 60mg/15 mL, NDC 0536-1001-85, Lot#22941601, Exp. Date 01/2018
- Diocto Syrup, Docusate Sodium 60mg/15 mL, NDC 0536-1001-85, Lot#22941602, Exp. Date 03/2018
- Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391515, Exp. Date 08/2017
- Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391516, Exp. Date 08/2017
- Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391517, Exp. Date 09/2017
- Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391518, Exp. Date 10/2017
- Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391520, Exp. Date 11/2017
- Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391521, Exp. Date 12/2017
- Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391601, Exp. Date 01/2018
- Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391603, Exp. Date 03/2018
- Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391604, Exp. Date 03/2018
- Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391606, Exp. Date 04/2018
- Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391607, Exp. Date 04/2018
- Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391609, Exp. Date 06/2018

Major:

- Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391517, Exp. Date 09/2017
- Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391518, Exp. Date 10/2017
- Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391519, Exp. Date 11/2017
- Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391601, Exp. Date 01/2018
- Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391602, Exp. Date 02/2018
- Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391604, Exp. Date 03/2018
- Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391605, Exp. Date 03/2018
- Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391608, Exp. Date 06/2018

Bayshore:

- Aller-chlor Antihistamine 120 mL, NDC 0536-1025-47, Lot# 23261501, Exp. Date 10/2017
- Sennazon Syrup, 237mL, NDC 7651810008, Lot#20391519, Exp. Date 11/2017

Centurion:

- Ninjacof, 473mL, NDC 23359-030-16, Lot#25291601, Exp. Date 03/2018
- Ninjacof A, 473mL, NDC 22359-033-16, Lot#25321601, Exp. Date 04/2018

Virtus:

- Virtrate-2, Sodium Citrate-Citric Acid, 473mL, NDC 69543-367-16, Lot#28601502, Exp. Date 11/2017
- Virtrate-2, Sodium Citrate-Citric Acid, 473mL, NDC 69543-367-16, Lot#28601601, Exp. Date 01/2018

- Virtrate-2, Sodium Citrate-Citric Acid, 473mL, NDC 69543-367-16, Lot#28601602, Exp. Date 03/2018
- Virtrate-2, Sodium Citrate-Citric Acid, 473mL, NDC 69543-367-16, Lot#28601603, Exp. Date 06/2018
- Virtrate-2, Sodium Citrate-Citric Acid, 473mL, NDC 69543-367-16, Lot#28601604, Exp. Date 06/2018
- Virtrate-K, Potassium Citrate and Citric Acid, 473mL, NDC 69543-262-16, Lot#28891502, Exp. Date 12/2017
- Virtrate-K, Potassium Citrate and Citric Acid, 473mL, NDC 69543-262-16, Lot#28891503, Exp. Date 12/2017

DIETARY SUPPLEMENT PRODUCTS

Rugby:

- Calcionate Syrup, Calcium Glubionate Syrup 473mL, UPC 005362770851, Lot#20341601, Exp. Date 06/2018
- Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471516, Exp. Date 11/2017
- Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471517, Exp. Date 11/2017
- Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471518, Exp. Date 11/2017
- Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471519, Exp. Date 11/2017
- Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471520, Exp. Date 11/2017
- Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471521, Exp. Date 12/2017
- Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471601, Exp. Date 01/2018
- Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471608, Exp. Date 04/2018
- Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471610, Exp. Date 05/2018
- Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471613, Exp. Date 05/2018
- Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471614, Exp. Date 06/2018
- D3 Vitamin Liquid, 50mL, UPC 005368400806, Lot#20691509, Exp. Date 11/2017
- D3 Vitamin Liquid, 50mL, UPC 005368400806, Lot#20691601, Exp. Date 01/2018
- D3 Vitamin Liquid, 50mL, UPC 005368400806, Lot#20691602, Exp. Date 02/2018
- D3 Vitamin Liquid, 50mL, UPC 005368400806, Lot#20691604, Exp. Date 05/2018
- Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461511, Exp. Date 10/2017
- Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461512, Exp. Date 10/2017
- Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461513, Exp. Date 11/2017
- Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461514, Exp. Date 11/2017
- Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461515, Exp. Date 12/2017
- Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461516, Exp. Date 12/2017
- Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461601, Exp. Date 02/2018
- Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461602, Exp. Date 02/2018
- Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461603, Exp. Date 04/2018
- Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461604, Exp. Date 04/2018
- Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461605, Exp. Date 05/2018
- Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461606, Exp. Date 05/2018
- Fer-iron Liquid, 50mL, UPC 005360710804, Lot#20901507, Exp. Date 07/2017
- Fer-iron Liquid, 50mL, UPC 005360710804, Lot#20901508, Exp. Date 11/2017
- Fer-iron Liquid, 50mL, UPC 005360710804, Lot#20901603, Exp. Date 05/2018
- Polyvitamin liquid with Iron, 50mL, NDC 0904-5100-50, Lot#21021510, Exp. Date 07/2017
- Polyvitamin liquid with Iron, 50mL, NDC 0904-5100-50, Lot#21021601, Exp. Date 01/2018
- Polyvitamin liquid with Iron, 50mL, NDC 0904-5100-50, Lot#21021602, Exp. Date 02/2018
- Polyvitamin liquid with Iron, 50mL, NDC 0904-5100-50, Lot#21021604, Exp. Date 05/2018
- Polyvitamin liquid, 50mL, NDC 0904-5099-50, Lot#20701511, Exp. Date 09/2018
- Polyvitamin liquid, 50mL, NDC 0904-5099-50, Lot#20701514, Exp. Date 12/2017
- Polyvitamin liquid, 50mL, NDC 0904-5099-50, Lot#20701605, Exp. Date 05/2018
- Polyvitamin liquid, 50mL, NDC 0904-5099-50, Lot#20701606, Exp. Date 06/2018
- Tri-Vitamin liquid, 50mL, UPC 005368501800, Lot#20731506, Exp. Date 08/2017
- Tri-Vitamin liquid, 50mL, UPC 005368501800, Lot#20731603, Exp. Date 02/2018

- Tri-Vitamin liquid, 50mL, UPC 005368501800, Lot#20731604, Exp. Date 06/2018
- Liquid Vitamin C, 118 mL, UPC 005360160975, Lot#20331510, Exp. Date 12/2017
- Liquid Vitamin C, 118 mL, UPC 005360160975, Lot#20331511, Exp. Date 12/2017
- Liquid Vitamin C, 118 mL, UPC 005360160975, Lot#20331601, Exp. Date 03/2018
- Liquid Vitamin C, 118 mL, UPC 005360160975, Lot#20331602, Exp. Date 03/2018

Major:

- CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471602, Exp. Date 01/2018
- CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471603, Exp. Date 02/2018
- CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471604, Exp. Date 02/2018
- CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471605, Exp. Date 03/2018
- CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471606, Exp. Date 03/2018
- CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471607, Exp. Date 04/2018
- CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471609, Exp. Date 05/2018
- CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471611, Exp. Date 05/2018
- CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471612, Exp. Date 05/2018
- Poly-Vita Drops, 50mL, NDC 0904-5099-50, Lot#20701509, Exp. Date 09/2017
- Poly-Vita Drops, 50mL, NDC 0904-5099-50, Lot#20701511, Exp. Date 09/2017
- Poly-Vita Drops, 50mL, NDC 0904-5099-50, Lot#20701513, Exp. Date 12/2017
- Poly-Vita Drops, 50mL, NDC 0904-5099-50, Lot#20701601, Exp. Date 02/2018
- Poly-Vita Drops, 50mL, NDC 0904-5099-50, Lot#20701602, Exp. Date 04/2018
- Poly-Vita Drops, 50mL, NDC 0904-5099-50, Lot#20701603, Exp. Date 04/2018
- Poly-Vita Drops, 50mL, NDC 0904-5099-50, Lot#20701606, Exp. Date 06/2018
- Poly-Vita Drops with Iron, NDC 0904-5100-50, Lot#21021510, Exp. Date 07/2017
- Poly-Vita Drops with Iron, NDC 0904-5100-50, Lot#21021601, Exp. Date 01/2018
- Poly-Vita Drops with Iron, NDC 0904-5100-50, Lot#21021602, Exp. Date 02/2018
- Poly-Vita Drops with Iron, NDC 0904-5100-50, Lot#21021603, Exp. Date 04/2018
- Poly-Vita Drops with Iron, NDC 0904-5100-50, Lot#21021604, Exp. Date 05/2018
- D-Vita Drops, 50mL, NDC 0904-6273-50, Lot#20691509, Exp. Date 11/2017
- D-Vita Drops, 50mL, NDC 0904-6273-50, Lot#20691510, Exp. Date 12/2017
- D-Vita Drops, 50mL, NDC 0904-6273-50, Lot#20691603, Exp. Date 03/2018
- D-Vita Drops, 50mL, NDC 0904-6273-50, Lot#20691605, Exp. Date 04/2018
- Ferrous Drops, 50mL, NDC 0904-6060-50, Lot#20901509, Exp. Date 11/2017
- Ferrous Drops, 50mL, NDC 0904-6060-50, Lot#20901510, Exp. Date 11/2017
- Ferrous Drops, 50mL, NDC 0904-6060-50, Lot#20901601, Exp. Date 02/2018
- Ferrous Drops, 50mL, NDC 0904-6060-50, Lot#20901602, Exp. Date 03/2018
- Ferrous Drops, 50mL, NDC 0904-6060-50, Lot#20901603, Exp. Date 05/2018
- Tri-Vita Drops, 50mL, NDC 0904-6274-50, Lot#20731506, Exp. Date 08/2017
- Tri-Vita Drops, 50mL, NDC 0904-6274-50, Lot#20731507, Exp. Date 11/2017
- Tri-Vita Drops, 50mL, NDC 0904-6274-50, Lot#20731604, Exp. Date 06/2018
- Tri-Vita Drops, 50mL, NDC 0904-6274-50, Lot#20731605, Exp. Date 06/2018

Bayshore:

- Pedia Tri-Vite Drops, 50mL, NDC 76518-020-50, Lot#20731506, Exp. Date 08/2017
- Pedia Tri-Vite Drops, 50mL, NDC 76518-020-50, Lot#20731508, Exp. Date 11/2017
- Pedia Tri-Vite Drops with Iron, 50mL, NDC 76518-040-50, Lot#21021511, Exp. Date 11/2017
- Pedia Poly-Vite Drops, 50mL, NDC 76518-030-50, Lot#20701512, Exp. Date 11/2017
- Pedia D-Vite Drops, 50mL, NDC 76518-050-50, Lot#20691509, Exp. Date 11/2017

Metron:

- Renew HC, Hydrolyzed Clinoptilolite, 30mL, Lot#30161601, Exp. Date 01/2018
- Renew HC, Hydrolyzed Clinoptilolite, 30mL, Lot#30161602, Exp. Date 03/2018
- Renew HC, Hydrolyzed Clinoptilolite, 30mL, Lot#30161603, Exp. Date 03/2018
- CytoDetox, Hydrolyzed Clinoptiloolite Fragments, 30mL, UPC 632687615989, Lot#30661601, Exp. Date 05/2018